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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/286,818	04/06/1999	RONALD L. REAM	P99.0082	5472

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[REDACTED] EXAMINER

TRAN, SUSAN T

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/286,818	Applicant(s) Ream et al.
	Examiner Susan Tran	Art Unit 1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on Jan 14, 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-12 and 19-22 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-12 and 19-22 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) All b) Some* c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>25</u> | 20) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt is acknowledged of applicants' Response to Notice of File Missing Parts filed 07/01/99, Corrected Filing Receipt filed 07/15/99, Information Disclosure Statement filed 10/07/99, 10/20/99, 10/29/99, 09/18/00, and Resubmission Information Disclosure Statement filed 04/02/01, Election filed 10/02/00, Request for Extension of Time filed 03/21/01, 09/17/01, Amendment A filed 03/21/01, Supplemental Information Disclosure Statement filed 09/17/01 and 12/07/01, Request for Continued Examine filed 09/17/01, and Request for Reconsideration filed 01/14/02.

Claim Rejections - 35 U.S.C. § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12, and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hausler et al. US 5,922,347.

Hausler teaches a stable chewing gum formulation that is tolerated by the mucous membrane, wherein the formulation comprises active drug (column 2, lines 8-56), filling, emulsifying, waxes, plasticising, and sugar (column 3, lines 11-67). The saliva content of medicament released is clearly inherent since Hausler obtains the same results desired by the

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applicant, i.e., a chewing gum formulation containing drug, and water-soluble content for oral mucosa.

Regarding to claims 2, 5, 10-12, and 19-22 the reference differs from the claimed invention by not specifically teaching the chewing gum is chewed for at least 2 minutes. However, it is within a skilled artisan to determine a suitable chewing time to obtain a desirable amount of drug to absorb through the oral mucosa.

The examiner notes that Hausler is silent as to the teaching of the chewing gum is being administered twice a day. However, it would have been obvious for one of the ordinary skill in this art to determine a suitable dosage according to the daily needed basis.

Response to Arguments

2. Applicant's arguments filed 01/14/02 have been fully considered but they are not persuasive. The examiner maintains the original rejections, and thus:

Claims 1-12, and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hausler et al. US 5,922,347.

Applicant argues that the transitional phrase "consisting of" in the generic claims excludes any element, step, or ingredient not specified in the claim. The examiner agrees to the limitation of the transitional phrase. However, applicant's claims recite "a method for delivering a medicament to an individual comprising", such language allows the present of other steps, elements. The transitional phrase "consisting of" in applicant's claims limit the ingredient of the chewing gum alone.

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Applicant argues that Hausler includes ASA , and therefore teaches away from the claimed invention. Contrary to the applicant's argument, the ASA in Hausler is used as an active agent, and therefore, reads over “at least one medicament” limitation.

Applicant argues that Hausler includes buffer agent, and thus teaches away from applicant's invention. However, it is the examiner's position that Hausler's buffer agent reads over applicant's “acidulants”.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
[Signature]